

**K913323 ETUDE (MODEL NUMBERS 24A05 & 24A06)**Sep 23, 1991  
60 days to decisionK913323 · Product code: **FAP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k913323/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Cystometric Gas (carbon-dioxide) On Hydraulic Device (FAP) |
| Date received         | Jul 25, 1991   |
| Decision date         | Sep 23, 1991   |
| Days to decision      | 60 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dantec Medical, Inc.</b>             |
| Location       | Mahwah, NJ, US                          |
| Contact        | RICHARD D MANTHEI                       |
| 510(k) history | 25 submissions · 25 cleared · 1990-1996 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913323/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 20, 2026